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4

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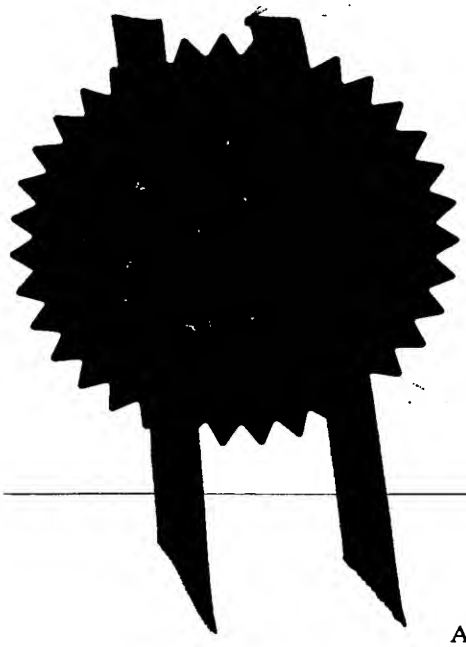

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. **Your reference** — 53.70681

2. **Patent application number** *(The Patent Office will fill in this part)* — 9917624.0

3. **Full name, address and postcode of the or of each applicant** *(underline all surnames)* — Summit Medical Ltd.
Bourton-on-the-Water
Gloucestershire, LG54 2 HQ
England

Patents ADP number *(if you know it)* — 6026215001

If the applicant is a corporate body, give country/state of incorporation — England

4. **Title of the invention** — Orthopaedic Bone Cement Mixing Container

5. **Name of your agent** *(if you have one)* — Frank B. Dehn & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)* — 179 Queen Victoria Street
London
EC4V 4EL

Patents ADP number *(if you know it)* — 166001

6. **If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and** *(if you know it)* **the or each application number**

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. **If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application**

Number of earlier application	Date of filing *(day / month / year)*

8. **Is a statement of inventorship and of right to grant of a patent required in support of this request?** *(Answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d)) — Yes

Orthopaedic Bone Cement Mixing Container

This invention relates to a container in which orthopaedic bone cement is mixed.

Orthopaedic bone cement is used throughout the world to secure hip, knee and other metallic protheses in an appropriate anatomical position.

Many different systems are available for mixing orthopaedic bone cement and the type of apparatus selected will depend on the personal preferences of the doctor or nurse mixing the cement, as well as the amount of cement being mixed and the type of materials being used.

Essentially, orthopaedic cement is made up of a powder component, e. g. polymethylmethacrylate powder, and a monomer, eg. g. methylmethacrylate monomer liquid, generally provided in an ampoule which is broken and added to the powder. The two components are then thoroughly mixed to provide a malleable cement which can be manipulated and applied to the appropriate bone parts, during surgery.

In order to avoid the cement becoming brittle, it is essential that the two components are very thoroughly mixed together and no 'dry' or 'dead' spots remain. Furthermore, as most cements set fairly quickly, it is important that the mixing can be quickly and easily carried out. This is, also, of course important as surgery should be carried out as quickly as possible for the comfort and safety of the patient.

Originally, the cement components were mixed, by hand, using a bowl and spatula. A theatre nurse would mix the appropriate quantities of the two components in the bowl and the physician would then take some of the mixed cement and mould it to the required shape, before inserting it into a preformed cavity or applying it to a resected bony surface where the prothesis is to be

One such mixing device is the bowl mixer forming the subject of European Patent No. 0616552. This system is preferred by many users as it is small and convenient to use and the mixing action is similar to that carried out in the above described manual bowl mixing technique and is one with which nurses are generally familiar.

Another mixing system is described in European Patent No. 0744991. In this arrangement, the cement is mixed in a cylindrical mixing chamber. The mixing mechanism comprises paddles rotatably mounted within the chamber. The paddles are rotated around the chamber by means of a 'barley twist' mechanism so that the user merely has to push the handle up and down, to cause rotation of the paddle. Furthermore, once the cement is mixed, this system can be converted into a syringe type dispenser by addition of a nozzle and plunger. There is thus no need to remove the mixed cement from the mixing chamber and transfer it to a dispenser.

Other similar mixing arrangements are known.

In all of these systems, the cement components need to be put into the mixing chamber. Generally, the nurse is provided with the cement powder, in a bag, and monomer ampoule. These are opened by the nurse, manually, and are introduced into the mixing chamber or bowl by means of funnels.

One problem is that when cutting open the cement powder bag and inserting the powder via the funnel, there is a certain degree of wastage due to spillage and cement clinging to the funnel. Furthermore, the opening and pouring of the cement powder caused a powder cloud which, within the regulated confines of the operating theatre, is unpleasant and may even have adverse effects on the theatre personnel.

These problems become more acute when time is very short and the mixing must be done extremely quickly, or with inexperienced theatre personnel.

One solution which has been considered is to

known cement mixing arrangements including the bowl mixer and syringe mixer described above. It may also be incorporated in mixing bowls where the mixing is carried out simply using a spatula etc.

The inner housing may be removable from the outer housing in any way, for example it may be in the form of a bag which is merely lifted out by the user, which opens on removal to drop the cement powder into the mixing chamber. In the most preferred embodiment, however, the inner housing is attached to or formed integrally with a lid provided on the container. The inner housing and the lid may, for example, be attached to each other by a snap fit arrangement or, indeed, by any other means of attachment. Thus, when the cement is to be mixed, the lid is removed by the user and as the lid is removed, it takes with it the inner housing.

To provide a secure container during transportation etc., the lid is preferably attached to the outer housing by means of a screw thread. Seals may also be provided.

The inner housing may be made of any materials suitable for containing the cement powder. Preferably, the material of which the inner housing is made is less rigid than that of the outer housing. This allows the inner housing to be compressed against the outer housing to provide a good seal at the open end of the inner housing.

It is important that, prior to removal of the inner housing, the cement is securely contained within the housing and, therefore, the 'open' end of the inner housing should form a seal with the outer housing or should be closed after filling.

Thus, in one embodiment, not shown, the inner housing has an open end into which the cement is inserted. This open end is then closed by any suitable means and the inner housing is placed within the outer housing in such a manner that when the inner housing is

fit arrangement 6. This creates a seal through which the cement powder cannot pass.

Fig. 2A shows how the cement is inserted into the inner housing, via the open end 7 of the housing.

The outer housing 3 incorporating the piston and base 8 is then fitted over the cement containing inner housing as shown in Fig. 2D.

Guide lips 9 may be provided on the outer surface of the inner housing to assist in the correct positioning of the outer housing relative to the inner housing.

The outer housing is then secured to the cap, by means of a screw thread 10, as shown in Fig. 2C. The open end of the inner housing, containing the cement, is provided with a seal 11, preferably a feather seal, which fully seals to the piston part of the outer housing to secure the cement powder within the inner housing. This results in a fully sealed packaged container, containing the cement powder within the inner housing, ready for use. The whole device is then packaged and sterilised for use.

A breather pad (not shown) may be provided on the cap so as to allow gas circulation to the cement.

As shown in Fig. 2D, when the cement is to be mixed, the user unscrews the cap 5 from the outer housing 2and lifts away the cap and the inner housing 3 connected thereto. As the inner housing is lifted away from the base of the outer housing, the cement powder 4 drops out of the inner housing into the mixing chamber 1. The cap and inner housing are then discarded and the standard mixing procedure for this type of mixing arrangement is carried out.

A similar procedure is used in relation to other mixing arrangements such as the bowl mixer 12 shown in Fig. 3. This may be a bowl as described in EP 0616552. The principle is essentially the same. An inner housing 3', containing the cement powder 4', is attached to the

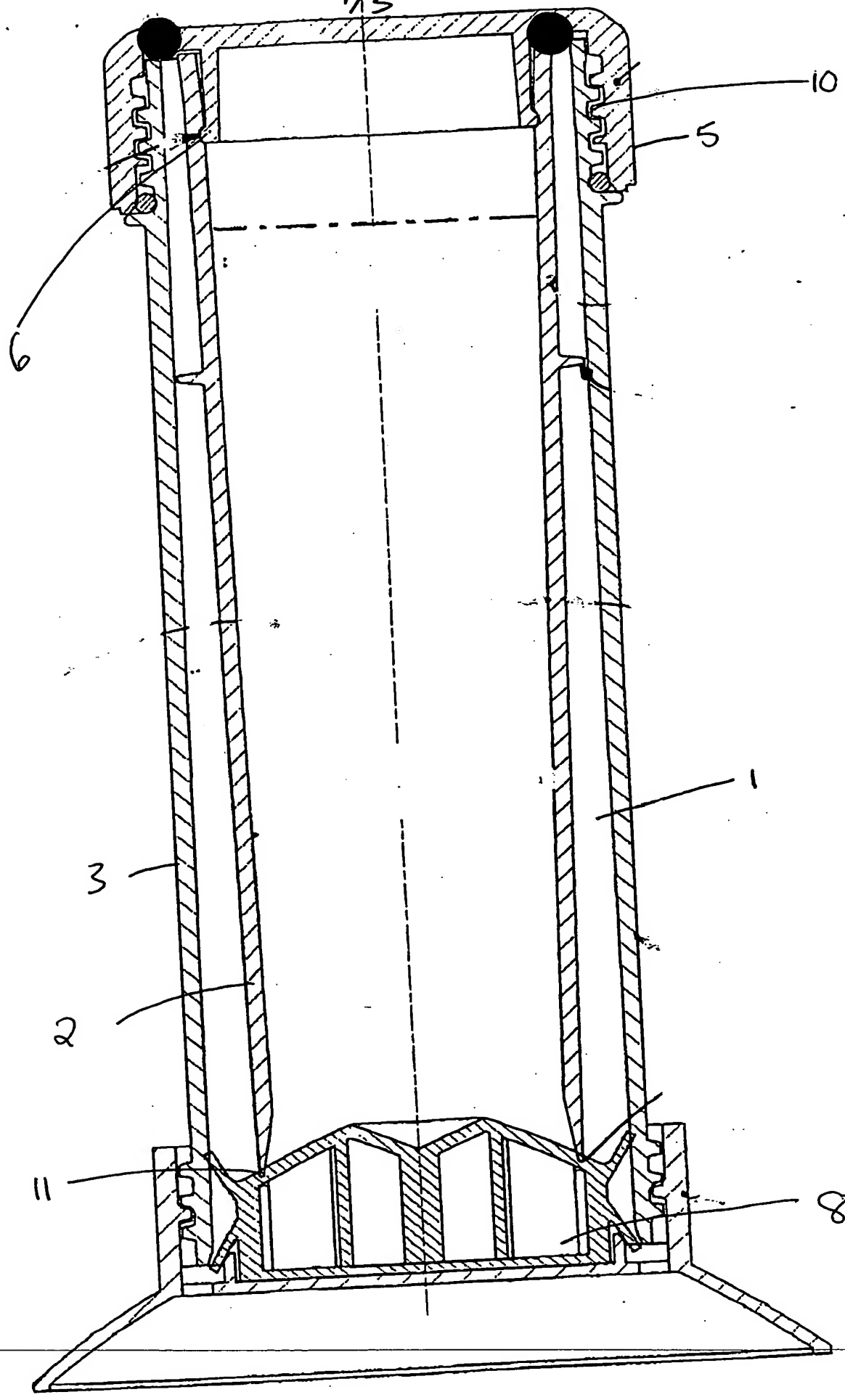

10
5
6
1
3
2
11
8

Fig 2D

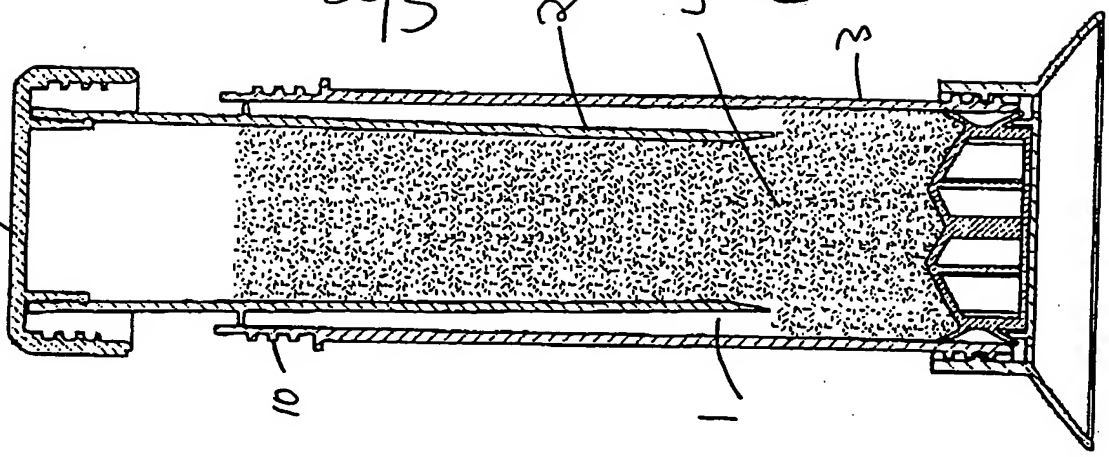


Fig 2C

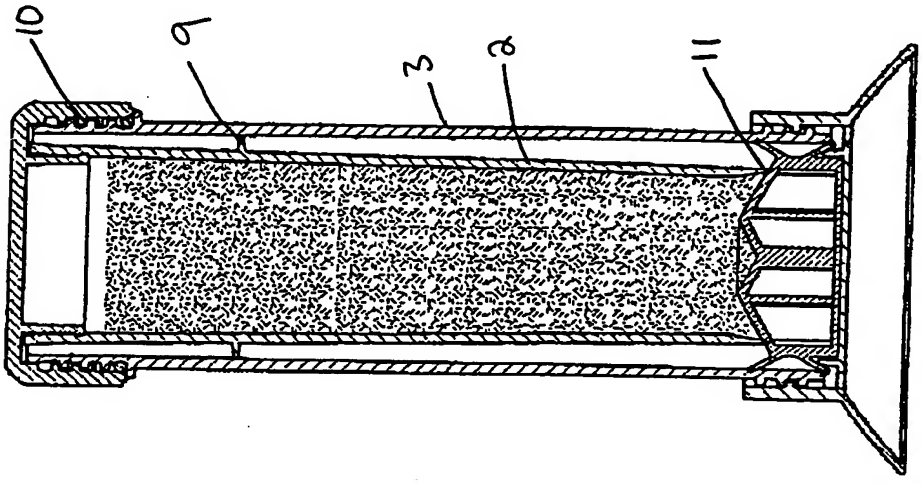


Fig 2B

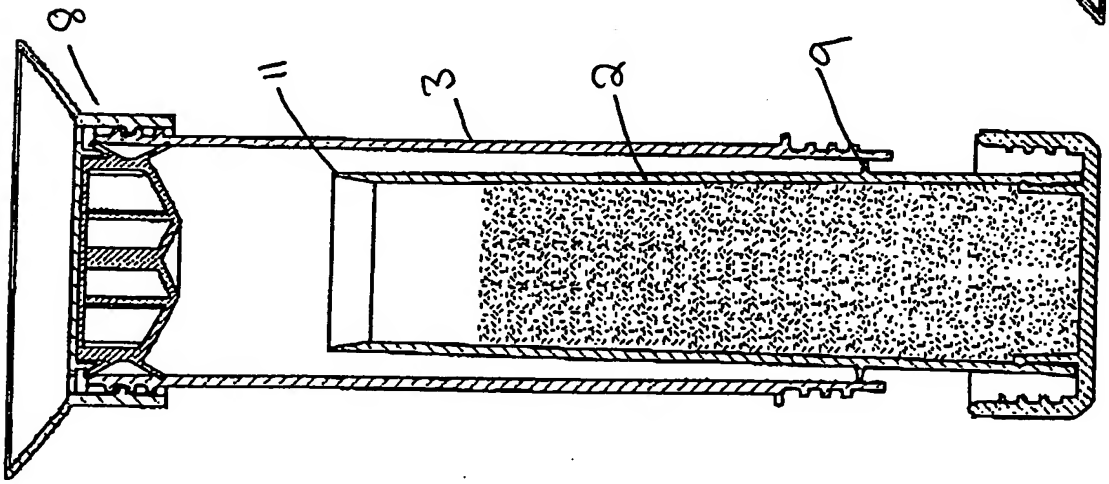
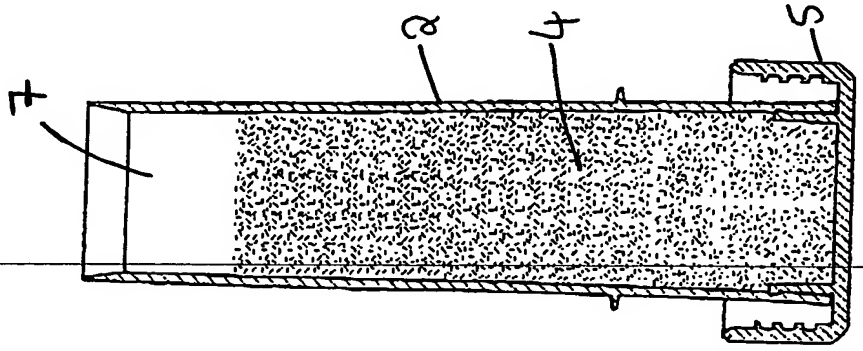


Fig 2A



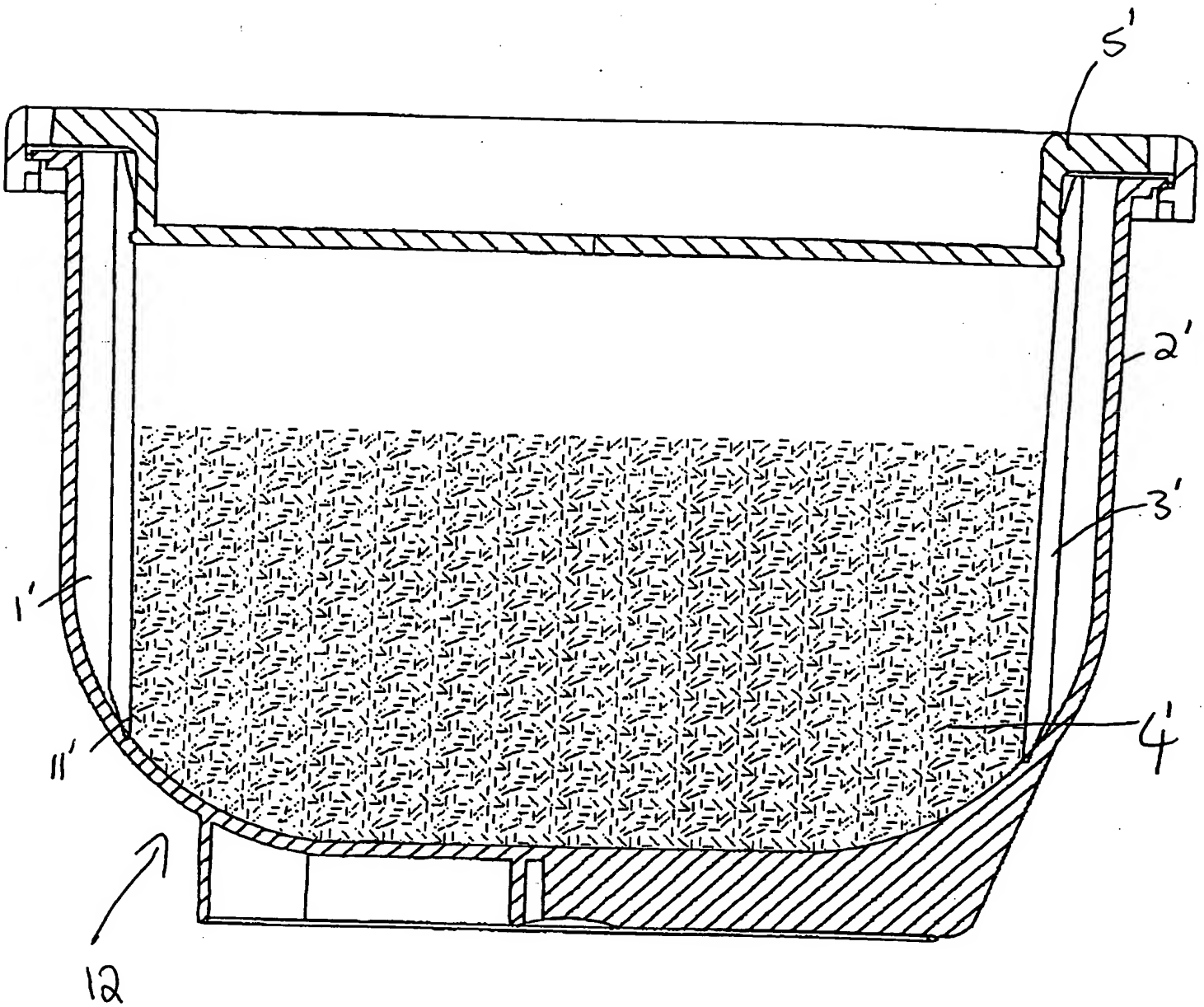


Fig. 3